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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,650	09/29/2000	Ursula Busse	1619.0080001/SRL/TBB	1706
26111	7590	01/05/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 01/05/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,650

Applicant(s)

BUSSE ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6, 9-11, 24, 26 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6, 9-11, 24, 26 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A (sequence alignment).

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/27/2005 has been entered.

Claims 4-6, 9-11, 24, 26, 35, and 36 are pending and examined on merits.

This Office action contains new ground of rejection.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 10 and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 4, 5, 10, 11, 24, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4 and 24 drawn to the newly added functional limitation “nucleic acid molecule is differentially expressed in a non-malignant prostate” are rejected for new matter. The specification at page 5 line 21 to page 6 line 2 discloses that the nucleic acid lacking the additional sequence (i.e. nucleotides 27 to 254 of SEQ ID NO: 1) is associated with prostate cancer whereas the RNA comprising same (i.e. SEQ ID NO:1 as claimed in the base claims 4 and 24) is associated with a non-malignant prostate state. The specification further discloses “Based on the differential expression of these two PCA3 RNA species, protocols for the diagnosis of prostate disease are provided”. Note the line bridging pages 5 and 6. This indicates “differentially expressed” encompasses association of the claimed product with both non-malignant and malignant prostate states, not just non-malignant prostate. The specification as originally filed does not have support for the claimed SEQ ID NO: 1 nucleic acid molecule being associated with both non-malignant and malignant prostate state. Amending the claims with functional language that has support in the specification as originally filed would obviate this part of the rejection. The dependent claims are also rejected because the functional limitation affects the dependent claims.

Allowable Subject Matter

The indicated allowability of claims 6, 9, and 26 is withdrawn in view of the newly discovered reference(s) to US Pat. 6,528,260 (Blumenfeld et al). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6 and 9 rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. 6,528,260 (Blumenfeld et al, with priority to 03/25/1999, and 04/30/1999).

Claims 6 and 9 are drawn to a primer and kit comprising said primer consisting of 10 to 50 consecutive nucleotides of nucleotide 27 to 254 of SEQ ID NO:1.

US Pat. 6,528,260 teach a primer and kit (note column 93, line 51, “kit” inherently has container according to entry “kit” in Merriam-Webster Online Dictionary downloaded on 12/27/05) comprising said primer consisting of 10 to 50 consecutive nucleotides of nucleotide 27 to 254 of SEQ ID NO:1.

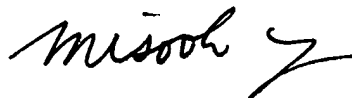
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

A handwritten signature in black ink, appearing to read "misook yu", with a stylized flourish at the end.

GenCore version 5.1.6
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OM nucleic - nucleic search, using sw model

Run on: December 1, 2005, 13:47:53 ; Search time 155 Seconds
(without alignments)
5802.879 Million cell updates/sec

Title: US-09-675-650-1

Perfect score: 506

Sequence: 1 caggagacacaaaggaagc.....ggcttcacagacatgcaac 506

Scoring table: IDENTITY NUC

Gapop 10.0, Gapext 1.0

Searched: 1303057 seqs, 889780828 residues

Total number of hits satisfying chosen parameters: 1289296

Minimum DB seq length: 10
Maximum DB seq length: 50

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database: Issued Patents NA.*

- 1: /cgm2_6/ptodata/1/ina/1 COMB.seq.*
- 2: /cgm2_6/ptodata/1/ina/5 COMB.seq.*
- 3: /cgm2_6/ptodata/1/ina/6A COMB.seq.*
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- 10: /cgm2_6/ptodata/1/ina/6 COMB.seq.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	22.6	4.5	47	3	US-09-671-317-711
2	21	4.2	47	3	Sequence 711, App
3	20.6	4.1	50	3	Sequence 66, Appl
4	20.2	4.0	48	2	Sequence 7842, Ap
5	20.2	4.0	48	3	Sequence 24, Appl
6	19.8	3.9	47	3	Sequence 6, Appli
7	19.8	3.9	48	2	Sequence 337, App
8	19.8	3.9	48	2	Sequence 1, Appli
9	19.8	3.9	50	3	Sequence 2, Appli
10	19.6	3.9	47	3	Sequence 1714, Ap
11	19.4	3.8	50	3	Sequence 3643, Ap
12	19.4	3.8	50	3	Sequence 33, Appl
13	19.4	3.8	50	3	Sequence 3643, Ap
14	19.2	3.8	25	3	Sequence 5392, Ap
15	19.2	3.8	50	3	Sequence 121545,
16	19	3.8	50	3	Sequence 1279, Ap
17	19	3.8	50	3	Sequence 6233, Ap
18	18.8	3.7	34	3	Sequence 6377, Ap
19	18.8	3.7	39	3	Sequence 12, Appl
20	18.8	3.7	42	3	Sequence 151, App
21	18.8	3.7	42	3	Sequence 233, App
22	18.8	3.7	42	3	Sequence 235, App
23	18.8	3.7	42	3	Sequence 23, Appl
24	18.8	3.7	42	3	Sequence 25, Appl
25	18.8	3.7	42	3	Sequence 233, App

C 25	18.8	3.7	42	3	US-09-790-417-235
C 26	18.8	3.7	47	3	US-09-671-317-646
C 27	18.8	3.7	47	3	US-09-422-978-657
C 28	18.8	3.7	50	3	US-10-131-827-6141
C 29	18.8	3.7	50	3	US-10-131-827-6198
C 30	18.8	3.7	50	3	US-10-131-827-6229
C 31	18.8	3.7	50	3	US-10-131-827-6370
C 32	18.6	3.7	44	6	PCT-US94-10617-17
C 33	18.6	3.7	45	2	US-08-171-389-322
C 34	18.6	3.7	45	2	US-08-123-936-322
C 35	18.6	3.7	45	2	US-08-475-228A-322
C 36	18.6	3.7	45	3	US-08-482-080A-322
C 37	18.6	3.7	45	3	US-09-354-947-322
C 38	18.6	3.7	45	3	US-09-993-346-322
C 39	18.6	3.7	45	6	PCT-US93-12388-322
C 40	18.6	3.7	47	3	US-09-671-317-964
C 41	18.6	3.7	47	3	US-09-422-978-1581
C 42	18.6	3.7	50	2	US-08-420-443-2
C 43	18.4	3.6	37	2	US-08-853-217-25
C 44	18.4	3.6	37	3	US-09-326-157-9
C 45	18.4	3.6	37	3	US-09-326-157-10

ALIGNMENTS

RESULT 1
US-09-671-317-711
; Sequence 711, Application US/09671317
; Patent No. 6528260
; GENERAL INFORMATION:
; APPLICANT: Blumenfeld, Marta
; APPLICANT: Chumakov, Ilya
; APPLICANT: Bougueret, Lydie
; APPLICANT: Cohen, Annick
; TITLE OF INVENTION: BIALLELIC MARKERS RELATED TO GENES INVOLVED IN DRUG METABOLISM
; CURRENT APPLICATION NUMBER: US/09/671.317
; CURRENT FILING DATE: 2000-09-27
; PRIOR APPLICATION NUMBER: US 09/536.178
; PRIOR FILING DATE: 2000-03-23
; PRIOR APPLICATION NUMBER: PCT/IB00/00403
; PRIOR FILING DATE: 2000-03-24
; PRIOR APPLICATION NUMBER: US 60/126.269
; PRIOR FILING DATE: 1999-03-25
; PRIOR APPLICATION NUMBER: US 60/131.961
; PRIOR FILING DATE: 1999-04-30
; NUMBER OF SEQ ID NOS: 977
; SOFTWARE: Patent.pm
; SEQ ID NO 711
; LENGTH: 47
; TYPE: DNA
; ORGANISM: Homo Sapiens
; FEATURE:
; NAME/KEY: allele
; LOCATION: 24
; OTHER INFORMATION: 12-504-428 : polymorphic base G or C
US-09-671-317-711

Query Match 4.5% ; Score 22.6 ; DB 3 ; Length 47 ;
Best Local Similarity 75.7% ; Pred. No. 1.1e+03 ;
Matches 28 ; Conservative 0 ; Mismatches 9 ; Indels 0 ; Gaps 0 ;

QY 62 AAATTTTGAAGGCTTAAAGTCTCTACTCGTTTCT 98
|||
DB 3 AGTTTATGAGCCCTTAGTCTCTCAGAGTTTCT 39

RESULT 2
US-09-422-978-66/c
; Sequence 66, Application US/09422978
; Patent No. 6537751
; GENERAL INFORMATION: